REMARKS

Formal Matters

Claims 32 to 40 are pending after entry of the amendments set forth herein.

Claims 32 to 40 were examined. Claims 32 to 40 were rejected.

Please replace Claim 32 with the clean version provided above.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached is captioned "**VERSION WITH MARKINGS TO SHOW CHANGES MADE.**"

Applicants respectfully request reconsideration of the application in view of the amendments and remarks made herein.

No new matter has been added.

Claim 32 has been objected to for typographical issues. In view of the above amendment to Claim 32, this rejection may be withdrawn.

Claims 32 to 40 have been rejected under 35 U.S.C. § 112, 1st ¶ as assertedly containing subject matter that was not sufficiently described in the specification so as to comply with the written description requirement. Specifically, the Examiner asserts that the broad genus of RNA polymerase promoters and reverse transcriptase enzymes that are elements of the claims are not supported by the written description of the specification as filed.

The MPEP at § 2163.02 provides the standard for satisfying the written description requirement:

> The courts have described the essential question to be addressed in a description requirement issue in a variety of ways. An objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). Under Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an

> applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed.

In the present case, the applicant is claiming a kit in which one of the elements is a primer-promoter, where the promoter component is an RNA polymerase promoter, and one of the elements in certain dependent claims is a reverse transcriptase, where these two components are not limited with respect to specific promoters are specific reverse transcriptases.

The specification provides extensive description of not just one, but a whole class of suitable promoters, where the description is both in general and specific terms, including listing out several representative specific RNA polymerase promoters. For example, with respect to the polymerase promoter component, the specification provides extensive description beginning at page 7, line 8, about the parameters of suitable promoters. The specification teaches that the promoter typically is between about 15 and 250 nt in length. The specification further teaches that the promoter is one to which RNA polymerase binds tightly and that contains a start site for RNA synthesis. In this portion of the specification, the specification also calls out three specific representative promoters, i.e., T7, T3 and SP6 whose sequences are known and readily obtained by those of skill in the art such that the applicant need not provide this sequence information in the specification. The specification also provides the sequence for the T7 promoter at page 13, line 2.

The Examiner contends that since the specification fails to provide any sequence but the sequence of the T7 promoter, the specification has not adequately described this element so as to convey to the public that the inventor was in possession of the genus of polymerase promoters at the time the specification was filed.

However, as pointed out above, the applicant has provided specific parameters in terms of physical and functional qualities by which one of skill in the

art can judge a candidate promoter to readily determine its suitability for inclusion in the claimed kits. Furthermore, the applicant has provided several specific representative promoters, the sequences of which are known to those of skill in the art. Clearly, the applicant envisioned a kit where a broad range of different promoters could be present, and so described these possible different promoters in the specification such that one of skill in the art would know that the Applicant was in possession of a kit where a variety of different primer promoters may be present, and not just a single type of promoter.

With respect to the reverse transcriptase component of the claims, the specification provides extensive guidance beginning at page 9 as to the types of reverse transcriptases that may be employed. The specification teaches that either a single activity or combination of two different activities may be employed. The specification also provides specific examples of commercially available activities that may be employed, e.g., MMLV-RT, Superscript II, etc. This teaching must be coupled with the knowledge of one of skill in the art of the variety of different reverse transcriptases that are known and commercially available. The sequences of a variety of different reverse transcriptases are known, including the sequences of the specific representative activities described in the specification. As such, failure to provide this specific sequence data does not fail the written description requirement.

When viewed in this light, the specification clearly demonstrates to one of skill in the art that the applicant was in possession of a kit in which not just a single type of reverse transcriptase could be present, but in fact a wide variety of different activities or combination of activities could be present.

In view of the above, it is respectfully submitted that the applicant has provided adequate written description for the pending claims and therefore the rejection of these claims under 35 U.S.C. § 112, 1st ¶ may be withdrawn.

Conclusion

The applicant respectfully submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone Gordon Stewart at 650 485 2386. The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16 and 1.17 which may be required by this paper, or to credit any overpayment, to Deposit Account No. 50-1078.

- Sequence Listing

Respectfully submitted,

Date: 6-28-01

By: _____
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VERSION WITH MARKINGS TO SHOW CHANGES MADE

32. (Amended) A kit for use in linearly amplifying mRNA, said kit comprising:

an oligonucleotide promoter-primer comprising an RNA polymerase promoter sequence; and

instructions to convert the mRNA to cDNA, and to then transcribe the cDNA into RNA in the presence of a reverse transcriptase that is rendered incapable of RNA-dependent DNA polymerase activity during this transcription step.